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DEC 21 2005

Office of Regulatory Policy HFD - 13 5600 Fishers Lane, Rockville, MD 20857

Attention: Claudia Grillo

Dear Ms. Axelrad:

Transmitted herewith are copies of applications for patent term extension for U.S. Patent No. 5,364,842 and U.S. Patent No. 5,795,864. The applications were filed on February 22, 2005, under 35 U.S.C. § 156.

The patents claim a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to Mary C. Till at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Senior Legal Advisor

Office of Patent Legal Administration Office of the Deputy Commissioner

for Patent Examination Policy

cc:

Charles E. Van Horn Finnegan, Henderson, Farabow, Garrett & Dunner, LLP 901 New York Ave, NW

Washington DC 20001-4413

RE: PRIALT® (ziconotide)

05E-0246 and 05E-0239 Docket No.